K122943

moor instruments
innovation in microvascular assessment

5 510(k) Summary

JAN 0 3 2013

Submitter information

Submitter:	Moor Instruments Ltd
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Establishment Reg No:	8043564
Date of preparation:	September 18th 2012

Device information

Trade name: moorFLPI-2 Full-Field Laser Perfusion Imager

Common name: Full-Field Laser Perfusion Imager

Classification name: Extravascular blood flow probe (21 CFR 870.2120, Product code DPT)

Predicate device: moorFLPI Full-Field Laser Perfusion Imager, 510(k) number K063586

The moorFLPI-2 is a device to perform non-contact imaging of tissue blood perfusion in the microcirculation, for example skin, using speckle contrast analysis. The tissue surface is illuminated with a diverging infra-red laser beam resulting in a laser speckle pattern. The pattern is imaged by a CCD camera and image processing of the speckle contrast is used to generate colour coded images of the tissue blood perfusion in the microcirculation.

5.1 Intended Use

The moorFLPI-2 Full-Field Laser Perfusion Imager is intended for blood flow measurements in the microcirculation. This device is intended for clinical research use.

5.2 Technological comparison to predicate device

The moorFLPI-2 Full-Field Laser Perfusion Imager uses the same technology and principle of operation as the predicate device whilst adding secondary features to improve ease of use. The intended use of both devices is the same.

5.3 Performance comparison to predicate device

The moorFLPI-2 was tested in direct comparison to the predicate device using laboratory models and skin blood flow measurements on volunteers.

5.4 Conclusions from testing

The moorFLPI-2 demonstrated performance, safety and effectiveness equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Moor Instruments, Limited
% Mr. Stewart Lillington
Product Development Manager
Mill Wey
Axminster, Devon
United Kingdom EX 135HU

January 3, 2013

Re: K122943
Trade/Device Name: moorFLPI-2 Full-Field Laser Perfusion Imager
Regulation Number: 21 CFR 870.2120
Regulation Name: Extravascular blood flow probe
Regulatory Class: Class II
Product Code: DPT
Dated: November 07, 2012
Received: November 13, 2012

Dear Mr. Lillington:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K122943

Device name: moorFLPI-2 Full-Field Laser Perfusion Imager

Indications for use:

The moorFLPI-2 Full-Field Laser Perfusion Imager is intended for blood flow measurements in the microcirculation. This device is intended for clinical research use.

Prescription Use: Yes (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use: No (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
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(Division Sign-Off)
Division of Surgical Devices

510(k) Number K122943